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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,336	07/05/2001	Richard A. Hudson	484482000300	5617

7590 04/09/2003

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EXAMINER

SACKEY, EBENEZER O

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/900,336

Applicant(s)  
HUDSON ET AL.

Examiner  
EBENEZER SACKY

Art Unit  
1626



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 16, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 28-39, 41, and 42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29, 31, and 42 is/are rejected.
- 7) ☒ Claim(s) 30, 32-39, and 41 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This is in response to applicants amendment B filed on 01/16/03.

Applicants have canceled claims 1-27 and 40 without prejudice or disclaimer and amended claim 28. Applicants have amended claim 28 for clarity to indicate that the alkyl, alkenyl, alkynyl, aromatic or cyclic aliphatic group of substituent "Y" has at least one  $\text{OSO}_3\text{R}^4$  moiety and, optionally, at least one OH moiety attached to it.

#### ***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "including" page 2, line 2 under definition of X may include elements other than those recited in the claim. See *Exparte Russell*, 153

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USPQ 752 (PTO Bd. App. 1966). Additionally, the phrase "a halogen with an atomic number from 9 to 53" is redundant and not necessary. It is suggested that the substituents, i.e.,  $R_1$  and  $R_2$  be defined as among others halogen. Additionally, in amended claim 28, page 2, line 8 after the structure, "N" should be change to --n--.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Ellison et al., "METABOLISM OF ORPHENADRINE CITRATE IN MAN" (Jour, of Pharm. And Exp. Therapeutics) Vol. 176, No. 2, pp 284-295.

Applicants claim a stilbene agent (compound) shown and defined in claim 28. Ellison et al., disclose derivatives of glucuronide/sulfate of o-

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methylbenzhydroxy acetic acid. See the entire publication, especially page 294.

***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 28, 29, 31 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlando et al. U.S. Patents 5,189,056 and 5,374,537 each taken alone. Applicants claim a stilbene agent (compound) depicted in claim 28. The substituents are as defined.

Determination of the scope and content of the prior art (MEP.. §2141.01)

Orlando et al., '056' and '537' disclose compounds (agents) for protecting stratified squamous epitheliums against noxious substances which generically corresponds to the claimed agents as note column 2, lines 3-9, column 4, lines 39-40, column 9, lines 49-50 of '056'; and column 2, lines 8-12, column 4, lines 41-42, column 8, lines 31-33, column 10, lines 44-48 of '537'. See compound shown on fig. 8 which corresponds to  $\text{CH}_3\text{CONH}$  and  $\text{SO}_3\text{H}$  when  $(\text{R}_1)_{n=2}$  and  $\text{SO}_3\text{H}$  and  $\text{NCS}$  when  $(\text{R}_2)_{n=2}$  or when each of  $\text{R}_1$  and  $\text{R}_2$  can be  $\text{NO}_2$ . See compound shown on fig. 9 of '056'.

Ascertainment of the difference between the prior art and the claims (MEP.. §2141.02)

The difference between the instant compounds and Orlando et al. is in the generic description of the compounds. The claimed agents (compounds)

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are a subgenus out of the generic disclosure of Orlando et al. See compound shown on fig. 8 which corresponds to  $\text{CH}_3\text{CONH}$  and  $\text{SO}_3\text{H}$  when  $(\text{R}_1)_{n=2}$  and  $\text{SO}_3\text{H}$  and  $\text{NCS}$  when  $(\text{R}_2)_{n=2}$  or when each of  $\text{R}_1$  and  $\text{R}_2$  can be  $\text{NO}_2$ . See compound shown on fig. 9 of '056'.

*Finding of prima facie obviousness---rational and motivation (MEP., §2142-2143)*

One of ordinary skill in the art would thus have been motivated to choose a subgenus out of the generic disclosure of '056' and '537' with the expectation of obtaining additional compounds (agents) which are useful for protecting stratified squamous epitheliums. The claimed invention would be obvious from the use of similar compounds of the reference in treating stratified squamous epitheliums absent of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that structurally similar compounds would have the same or virtually the same properties. The instantly claimed agents would have been suggested to one of ordinary skill absent a showing of unexpected results or properties.

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Claims 30, 32-39 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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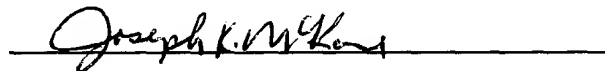
Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

April 7, 2003

A handwritten signature in cursive script, reading "Joseph K. McKane", is written over a horizontal line.

Joseph K. McKane

Supervisory Patent Examiner



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Art Unit 1626, Group 1600

Technology Center 1